

The article in the Detroit lot was alleged to be misbranded further in that the statement, "Each Tablet Contains Phenobarbital 1 Gr.," appearing on its label, was false and misleading as applied to an article which did not contain, in each tablet, 1 grain of phenobarbital. It was alleged to be adulterated in that its strength differed from that which it was represented to possess.

On February 21 and May 19, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

1153. Adulteration and misbranding of Akerite Glycerin Alternate B-100 (glycerin substitute or alternate). U. S. v. Akerite Chemical Works, Inc. Plea of guilty. Fine, \$3,004 and costs. (F. D. C. No. 9679. Sample Nos. 6594-F, 2333-F, 23346-F.)

On October 25, 1943, the United States attorney for the Northern District of Illinois filed an information against the Akerite Chemical Works, Inc., Chicago, Ill., alleging shipment of quantities of the above-named product from the State of Illinois into the States of Missouri and Pennsylvania on or about September 9, 1942, and January 20 and February 4, 1943.

It was also alleged in the information that prior to the dates of the 1943 shipment the defendant represented the article as a nontoxic substitute for glycerin by causing to be prepared and distributed a circular entitled "Akerite Glycerin Substitute," which contained the following statements: "Akerite Glycerin Substitute is an aqueous solution derived from dextrin, starch and corn sugar by a special process. It is non-toxic"; and that prior to the date of the 1942 shipment the defendant represented the article as a nontoxic alternate for glycerin by means of a written communication, addressed by the defendant to the consignee, which contained the following statement: "Glycerin Alternate * * * Akerite Glycerin Alternative, an aqueous nontoxic liquid derived mainly from corn."

The article was alleged to be adulterated in that it was represented as a nontoxic substitute or nontoxic alternate for glycerin, which is a nonpoisonous substance, whereas the article consisted in large part of diethylene glycol, a poisonous chemical compound. It was alleged to be further adulterated in that a toxic substance, i. e., a substance containing diethylene glycol, had been substituted in whole or in part for the article.

A portion of the article (two shipments) was alleged to be misbranded because of false and misleading statements on the labels which represented and suggested that it was a substitute for glycerin, a nonpoisonous substance.

It was also alleged in the information with respect to the two shipments that the article was a new drug since it was not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions suggested in its labeling, i. e., "Glycerin Substitute," and application filed pursuant to the law was not effective with respect to the article.

On December 30, 1943, the defendant having entered a plea of guilty, the court imposed a fine of \$1,000 on each of the 3 counts charging adulteration, and a fine of \$1 on each of the other counts, a total fine of \$3,004 plus costs.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1154. Misbranding of Sano. U. S. v. William J. Nassano (Sano Medicine Co.) Plea of guilty. Fine, \$250 and costs. (F. D. C. No. 10619. Sample No. 46330-F.)

On February 3, 1944, the United States attorney for the Northern District of Ohio filed an information against William J. Nassano, trading as the Sano Medicine Co., Cleveland, Ohio, alleging shipment of a quantity of Sano on or about February 7, 1943, from the State of Ohio into the State of Virginia.

Analysis disclosed that the article consisted of a brown liquid with sediment, containing water, alcohol, and plant extractives, including emodin-bearing drugs and a trace of unidentified alkaloids.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that the article was a diuretic and a tonic; that it would be efficacious as an internal medicine and aid in the relief of rheumatism; that it would assist in eliminating uric acids

and toxins from the system; and that it would be efficacious in removing the cause of uric acids and toxins in the system.

It was alleged to be further misbranded in that its labeling did not bear adequate directions for use since the directions provided for taking the article three times each day, whereas the article was a laxative and should be taken only occasionally and as needed; and in that its labeling failed to warn that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, or that frequent or continued use might lead to a dependence on laxatives to move the bowels.

On March 1, 1944, the defendant entered a plea of guilty and the court imposed a fine of \$250 and costs.

1155. Misbranding of Hamby's Dawson Springs Water. U. S. v. Dawson Springs Water Co., Inc., and William R. Whitford. Pleas of guilty. Fines, \$125 plus costs against each defendant. (F. D. C. No. 10617. Sample No. 42273-F.)

On February 15, 1944, the United States attorney for the Western District of Kentucky filed an information against the Dawson Springs Water Co., Inc., Dawson Springs, Ky., and William R. Whitford, president, alleging shipment on or about March 25, 1943, from the State of Kentucky into the State of Tennessee of a quantity of the above-named product.

Analysis disclosed that the article consisted essentially of Epsom salt and sodium sulfate, with small proportions of sodium chloride and calcium sulfate, and water. The carton in which the bottle containing the article was packed was materially larger than necessary.

The article was alleged to be misbranded (1) since it was a laxative and its labeling failed to warn that it should not be used when abdominal pains, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence on laxatives to move the bowels; (2) in that its container was so made, formed, and filled as to be misleading; and (3) in that the statements appearing in its labeling which represented and suggested that the article consisted essentially of natural mineral spring water and derived its physiological activity principally from water obtained from natural mineral springs were false and misleading since the article consisted essentially of magnesium sulfate (Epsom salt) and sodium sulfate dissolved in water, and it derived its physiological activity in greater part if not entirely from its content of added magnesium sulfate and sodium sulfate.

The article was alleged to be misbranded further because of false and misleading statements in its labeling which represented and suggested that it would aid in natural elimination; that it would be effective as an alterative and blood tonic; that it would be healing to the mucous membrane; that it would be valuable in the treatment of all diseases of the teeth, bone, skin, and blood; that it would aid digestion and be of value in the treatment of diabetes; that it would appreciably neutralize acid in the stomach; that it was of value as a liver medicine and would act on the kidneys and aid in the treatment of rheumatism and gout; that it would stop secretion of uric acid, correct phosphate in the urine, and be of value in the treatment of Bright's disease; that it was a diuretic for rheumatism, gout, gravel, dropsy, gall stones, and similar conditions indicated by the abbreviation "etc."; that it was a tonic and nerve sedative, and would promote secretion of urine and be of value in the treatment of gastric disturbances, stomach troubles, indigestion, and the similar conditions indicated by the abbreviation "etc."; and that it was a valuable kidney remedy.

On May 1, 1944, the defendants having entered pleas of guilty, the court imposed a fine of \$125 plus costs against the corporate defendant, and a fine of \$125 plus costs against the individual defendant.

1156. Misbranding of Balm and Kru-Lax. U. S. v. Carl Fred Krueger (Oriental Laboratory). Plea of guilty. Fine, \$200. Sentence of 6 months in jail suspended and defendant placed on probation for 3 years. (F. D. C. No. 10625. Sample Nos. 46414-F, 46415-F.)

On January 29, 1944, the United States attorney for the Eastern District of Missouri filed an information against Carl Fred Krueger, trading as the Oriental Laboratory, St. Louis, Mo., alleging shipment from the State of Missouri into the State of Illinois of a quantity of Balm on or about March 22, 1943, and a quantity of Kru-Lax on or about April 8, 1943.

Analysis of the Balm disclosed that it consisted of small proportions of carbolic acid, creosote, camphor, and pine tar, incorporated in a base of petrolatum.